REMARKS

This Amendment is submitted in reply to the Office Action mailed on March 10, 2005. In the Office Action, the Examiner rejected claims 13-30 and 38-49. With this Amendment, claims 13, 17-18, 21-22, 24-25, 27-30, 43, and 45 are amended; claim 38 is canceled, and new claims 50-51 are added. Upon entry of this Amendment, the above-identified application will include claims 13-30 and 39-51.

Though claim 38 is canceled via this Amendment, Applicant continues to believe claim 38 is allowable, as originally presented in the above-identified application and also as this claim presently exists as of the present request to cancel claim 38. Likewise, though claims 13, 17-18, 21-22, 24-25, 27-30, 43, and 45 are amended via this Amendment, Applicant continues to believe claims 13, 17-18, 21-22, 24-25, 27-30, 43, and 45 are allowable, as originally presented in the above-identified application and as these claims presently exist as of the present request to amend these claims. Therefore, Applicant is canceling claim 38 and amending claims 13, 17-18, 21-22, 24-25, 27-30, 43, and 45 without prejudice to Applicant's right to pursue claims worded like claims 13, 17-18, 21-22, 24-25, 27-30, 38, 43, and 45, as originally presented or as worded subsequent to original presentation, in the above-identified application or in a continuation application that is based on the above-identified application.

Furthermore, no claim amendment and no claim cancellation made herein is related to any statutory patentability requirement unless expressly stated herein. Also, no claim amendment made herein is made for the purpose of limiting (narrowing) the scope of any claim.

Examiner's Objection To The Specification

In the Office Action, the Examiner objected to the specification of the above-identified application since the address of the American Type Culture Collection has changed since the above-identified application was filed. According to the Examiner:

> Page 17 of the specification (bottom of page) contains an address for the ATCC which is out of date. The current address is American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209. The specification should be brought up to date via an amendment.
>
> Appropriate correction is required.

As indicated above, Applicant has requested replacement of the paragraph appearing at page 17, line 28, through page 18, line 4, with a new paragraph that includes the current address of the American Type Culture Collection. This amendment is believed to satisfactorily address the Examiner's objection to the specification. Consequently, reconsideration and withdrawal of the objection to the specification is respectfully requested.

Examiner's Objection to the Claims

In the Office Action, the Examiner objected to claims 17 and 18 under 37 C.F.R. §1.75(c) as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. According to the Examiner:

> The instant claims depend from base claims which have two requirements: 1) the DNA molecule must encode a bovine adipocyte leptin and 2) must hybridize to a specified sequence. The dependent claims 17-18 place size limitations on the DNA of 'at least 20' or 'at least 50 bases', which is no where near the necessary size of a DNA which will encode a bovine leptin polypeptide, absent evidence to the contrary. Therefore, the claims do not appear to further limit the claims from which they depend.

In this regard, the Examiner also stated:

> Molecules of this length would encode a fragment, and claims of this nature could be presented as independent claims or they could be presented in a different manner so as to not include the requirement that they encode "bovine adipocyte polypeptide leptin".

Applicants have amended claims 17 and 18, as indicated above, to incorporate the Examiner's suggestion. Now, claims 17-18, which read as follows, are believed to properly depend from independent claim 13:

> *17. (Currently Amended) The isolated single or double-stranded DNA molecule of claim 13 wherein the isolated DNA molecule is at least about 20 bases and encodes at least a fragment of the bovine leptin polypeptide that hybridizes to the nucleotide sequence of SEQ ID NO: 3 under stringent hybridization conditions.*
>
> *18. (Currently Amended) The isolated single or double-stranded DNA molecule of claim 13 wherein the isolated DNA molecule is at least about 50 bases and encodes at least a fragment of the bovine leptin polypeptide that hybridizes to the nucleotide sequence of SEQ ID NO: 3 under stringent hybridization conditions.*

Claims 17 and 18 are believed to properly depend from independent claim 13. Consequently, Applicant respectfully asks the Examiner to reconsider and withdraw the objection to claims 17-18 under 37 C.F.R. §1.75(c) and that claims 17-18 be allowed.

Next, the Examiner objected to claims 38-42, 44, and 46 under 37 C.F.R. §1.75(c) as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. According to the Examiner:

> Claims 38-42, 44, 46 are objected to under 37 CFR 1.75(c), as being of improper dependent form for falling to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

> The recited claims and the claims from which they depend all recite language regarding encoding "bovine adipocyte polypeptide leptin" or "bovine leptin polypeptide". However, the instant specification only describes a single protein of leptin which has been isolated from cows, making it bovine leptin (SEQ ID NO:4). Specifically, the specification indicates at page 2 "this invention is directed to a bovine adipocyte polypeptide (i.e., the bovine leptin protein)" and uses the terms "bovine adipocyte polypeptide" and "bovine leptin" interchangeably as meaning the same protein throughout the specification (see page 5 for example). Therefore, the further dependent claims which recite that the encoded protein is "bovine leptin" is not further limiting. .

In regard to Applicant's usage of both the term "bovine adipocyte polypeptide leptin" and the term "bovine leptin polypeptide" in different claims, the Examiner also stated:

> These recitations are used separately as well as in conjunction with one another as if to denote a distinction between the molecules which are encoded. However, a fair reading of the instant specification would indicate that the above recitations all refer to the same protein, which is leptin produced in cows.

Applicant agrees with the Examiner's characterization of "bovine adipocyte polypeptide leptin" and "bovine leptin polypeptide" as each referring to bovine leptin produced in cows, and further emphasizes the bovine leptin may be obtained from anywhere such bovine leptin may be found within the cow. Consequently, Applicant has amended claims 39-42 and 44, as indicated above to recite bovine leptin polypeptide, and incorporate the Examiner's suggestion. Claim 46 already recited bovine leptin polypeptide. Claims 39-42, 44, and 46 are believed to properly depend from independent claims 22, 24, 25, 27, 43, and 45, respectively. Therefore, Applicant respectfully asks the Examiner to reconsider and withdraw the objection to claims 39-42, 44, and 46 under 37 C.F.R. §1.75(c) and that claims 39-42, 44, and 46 be allowed.

Claim Rejections Under the Written Description Requirement of the First Paragraph of 35 U.S.C. §112

In the Office Action, the Examiner rejected claims 13-30 and 38-49 under the first paragraph of 35 U.S.C. §112 for allegedly failing to provide an adequate written description. In support of this rejection, the Examiner stated:

> Claims 13-30 and 38-49 are rejected under 35 U.S.C. 112, first paragraph, as falling to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed Invention.
>
> The instant claims are generically directed to isolated DNA and RNA which encode bovine leptin, wherein the nucleic add molecule hybridizes to a nucleic acid sequence of SEQ ID NO:3 (or a variant thereof) under stringent hybridization conditions.

> However, the only such molecule disclosed in the instant specification is the nucleic acid molecule of SEQ ID NO:3 which encodes the protein of SEQ ID NO:4.

Applicant believes claims 13-30 and 39-49 do satisfy the written description requirement, despite the Examiner's rejection of claims 13-30 under the written description requirement of the first paragraph of 35 U.S.C. §112.

As indicated above, claim 38 has been cancelled, since claim 38, after amending to address the Examiner's objection to claim 38, was merely a duplicate of claim 13. Applicant's cancellation of claim 38 is in no way related to the Examiner's rejection of claim 38 under the written description requirement.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. However, the examiner has the initial burden of presenting evidence or reasons why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims.

Based on the Examiner's remarks recited above, the Examiner apparently contends that disclosure of the structure (sequence) of only one molecule allegedly limits an inventor to only claiming that single molecule. However, that is a gross oversimplification that avoids structural requirements and certainty that is inherent in the language of claims 13-30 and 39-49. Besides this focus on the single sequence structure, the Examiner also draws some conclusions from a Declaration presented by the inventor in a related application. However, as explained below, the Examiner's conclusions miss the point of this Declaration and over generalize some points made by the inventor in the Declaration. Finally, while admitting there is at least a "partial" disclosure of structure in the claims due to the recited hybridization characteristic, the Examiner fails to give adequate weight to the preamble recitation of the claims and fails to consider the structural implications o the encoding language used in the claims.

First, we consider the "isolated . . . DNA molecule" language present in the preamble of claims 13-28 and 44:

> In contrast, use of less specific, generic preamble language, such as "composition," "nucleic acid," "DNA," and "RNA," does not typically present a written description problem. These terms are sufficiently general that one skilled in the art can readily envision a sufficient number of members of the claimed genus to provide written description support for the genus.

Request for Comments on Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 ¶1 "Written Description" Requirement, Docket No. 980605148-8148-01, June 9, 1998; available on August 9, 2005 at www.uspto.gov/web/offices/com/sol/og/1998/week27/patappl.htm. Though the preamble language of claims 29-30, 39-43, and 45-49 falls outside this passage, the language of the preamble is only one part o the equation regarding structural description.

The Examiner recognizes that one species falling within the scope of the claims was in the possession of the inventor at the time the priority application of the present application was filed. Based on possession of this species, the question is whether one of ordinary skill in the art would recognize that still other related species falling within the claims are in the possession of the inventor. The answer to this question is yes. The claims and the application disclose use of stringent hybridization conditions. Such use of stringent hybridization conditions is known in the art to yield structurally similar molecules such that one of ordinary skill in the art would not expect substantial variation among species encompassed within the scope of the claims.

The single disclosed species is representative of other species falling within the scope of the claims because reduction to practice of the single species acknowledged by the Examiner, considered along with the stringent hybridization conditions defined in the claims and the level of skill and knowledge in the art, are sufficient to allow the skilled artisan to recognize the inventor was in possession of the necessary common attributes or features of the elements possessed by the members of the genus. This analysis dovetails with the analysis provided for analogous fact patterns in Examples 9 and 10 in the Synopsis of Application of Written Description Guidelines available at http://www.uspto.gov/web/menu/written.pdf. The foregoing comments demonstrate the inventor did in fact have possession of the invention of the present application, as presently defined in the claims of the above-identified application.

As mentioned above, the Examiner places abundant emphasis on a Declaration presented by the inventor in a related application:

> In the parent application (08/688,908), to which the instant application claims priority, the inventor, Michael E. Spurlock, filed a Declaration under 37 C.F.R. 1.132 regarding isolation of the leptin gene using murine or human leptin as a probe. However, the comments made regarding using a murine or human sequence as a probe are also applicable to using a bovine sequence to isolate other related intraspecies molecules. At paragraph 5 of the Declaration, Dr. Spurlock states "intraspecies homology also presents an obscuring factor in isolating a particular gene in one species using primers derived from a different species.

> Specifically, multiple genes in the target species may each have similarly high homology to the same primers based on a known gene of another species. Separating and purifying highly homologous intraspecies genes is difficult with the difficulty increasing as the homology increases. At paragraph 6 of the Declaration, Dr. Spurlock states "The bottom line is that you do not know **the bovine leptin sequence** until you have **the bovine leptin sequence**. Even then, you may have variations within the species because of the genetic diversity that exists within all species populations. Some of these variations may be very important relative to the functionality of the protein".

Emphasis added. The Examiner takes these comments and apparently reaches the conclusion that actual reduction to practice is the only way an inventor could ever have possession of multiple species:

> Based on these statements by Applicant, it is clear that one of ordinary skill in the art would not know **bovine leptin** until they had **bovine leptin**.

However, this is an erroneous conclusion. For purposes of clarification, we look at the entire passage of Dr. Spurlock the Examiner refers to:

> In my opinion, knowing the sequence of a murine or human leptin gene does not allow one skilled in the art to know or contemplate the exact sequence of a leptin gene in another species such as bovine. Rather, such knowledge of the murine and human leptin gene sequences merely provides a good starting point for determining the bovine leptin gene sequence. For example, one skilled in the art could predict from the murine or human leptin sequence that the bovine leptin sequence would have high homology overall and would likely have parts of the sequence wherein the homology was 100%. However, one skilled in the art could not predict the actual homology between these species nor where the regions of 100% homology occur within the sequences. Even assuming a homology of about 85%, each codon in the murine sequence would have a 1-in-6 chance, at random, of being different in the bovine sequence. But merely knowing the murine sequence along with the homology does not provide any guidance as to which particular nucleotides or codons differ between species. The bottom line is that you do not know the bovine leptin sequence until you have the bovine leptin sequence. Even then, you may have variations within the species because of the genetic diversity that exists within all species populations. Some of these variations may be very important relative to the functionality of the protein.

First, as emphasized in the passages above, Dr. Spurlock is concerned with differences between leptin of different species, though the Examiner attempts to blur this distinction. Next, Dr. Spurlock merely emphasizes that prevention of hybridization of different leptin molecules becomes more difficult as regions of similar homology increase between different leptin

molecules. However, such hybridization issues are addressed by the claims and description of the present application by specifying stringent hybridization conditions be employed.

As to the functionality comment by Dr. Spurlock, the Examiner elsewhere in the Office Action equates this to a lack or very low level of encoded functionality. However, such a conclusion is difficult to maintain when one realizes Dr. Spurlock does not indicate what he means by functionality. Any conclusion to the contrary, including the Examiner's conclusion, is purely speculative and therefore meaningless.

Ultimately, Dr. Spurlock's Declaration comments relied upon by the Examiner merely indicate the desirability of employing stringent hybridization conditions, as addressed by the claims and description of the present application, to attain better specificity. Though the Examiner seeks to rely on the "functionality" comment elsewhere in the present Office Action, this attempt represents pure speculation with no definitive conclusion attainable.

Based on the weight of the evidence, it is evident the inventor did in fact have possession of the invention of the present application, as presently defined in the above-identified application. Claims 13-30 and 39-49 are believed allowable. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 13-30 and 39-49 under the written description requirement of the first paragraph of 35 U.S.C. §112 and that claims 13-30 and 39-49 be allowed.

Claim Rejections Under the Enablement Requirement of the First Paragraph of 35 U.S.C. §112

In the Office Action, the Examiner rejected claims 13-30 and 38-49 under 35 U.S.C. §112, first paragraph, as allegedly failing to satisfy the enablement requirement:

> The claim(s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Despite the Examiner's comments, claims 13-30 and 38-49 are enabled by the disclosure in accordance with the first paragraph of 35 U.S.C. §112.

As indicated above, claim 38 has been cancelled, since claim 38, after amending to address the Examiner's objection to claim 38, was merely a duplicate of claim 13. Applicant's cancellation of claim 38 is in no way related to the Examiner's rejection of claim 38 under the written description requirement.

The dispute that is the basis of this enablement rejection centers on the meaning of the term "encode" and the ability of shorter nucleotides to encode bovine leptin. The Examiner does not challenge Applicant's contention that the application provides appropriate details explaining how to practice the present invention, as defined in claims 38-49. Instead, the Examiner challenges the veracity of the statement on the basis that the Examiner believes Applicant's definition of encode is erroneous. Applicant has provided evidence to the Examiner demonstrating support for Applicant's definition of encode. See the discussion on pages 21 and 23 of the Amendment After Final filed in response to the Final Office Action dated June 16, 2004 along with the article by Y.M. Kennes, B.D. Murphy, F. Pothier and M.-F Palin, entitled Characterization of Swine *Leptin (Lep)* Polymorphisms and Their Association with Production Traits (2001) attached as Exhibit A of the Amendment After Final filed in response to the Final Office Action dated June 16, 2004.

The Kennes article demonstrates, despite the Examiner's allegation to the contrary, that the scientific literature does indeed recognize nucleic acid molecules having at least about 20 bases of a nucleotides sequence derived from a leptin gene that encodes a leptin molecule. The Examiner continues to allege "the art does not recognize a nucleic acid as short as 20-50 nucleotides long that encodes a leptin molecule." However, despite the fact Applicant has provided evidence in support of Applicant's understanding of the meaning of "encode," the Examiner has not yet produced any such evidence in support of the Examiner's contention that Applicant's interpretation is wrong. Since Applicant has demonstrated the specification disclosure, on its face, teaches how to make and use the invention defined in the claims, the Examiner is obligated, under In re Wright, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993)., to back up the Examiner's assertions controverting the truth and accuracy of any enabling statements in dispute, including the meaning of "encode," with acceptable evidence or reasoning explaining why the enabling statement is believed untrue or inaccurate. The Examiner's mere allegation about what the art does not recognize, without more, is insufficient to carry the Examiner's obligation under Wright.

Claims 13-30 and 39-49 are believed allowable. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 13-30 and 39-49 under the enablement requirement of the first paragraph of 35 U.S.C. §112 and that claims 13-30 and 39-49 be allowed.

Claim Rejections Under the Second Paragraph, 35 U.S.C. §112

In the Office Action, the Examiner rejected claims 13-30 and 38-49 under the second paragraph of 35 U.S.C. §112 as allegedly "being indefinite for failing to particularly point

out and distinctly claim the subject matter which applicant regards as the invention." Despite the Examiner's various comments in support of these rejections, Applicant believes Claims 13-30 and 38-49 are definite within the meaning of the second paragraph of 35 U.S.C. 112

As indicated above, claim 38 has been cancelled, since claim 38, after amending to address the Examiner's objection to claim 38, was merely a duplicate of claim 13. Applicant's cancellation of claim 38 is in no way related to the Examiner's rejection of claim 38 under the definiteness requirement.

In one aspect, the Examiner challenged Applicant's use of "a" or "an" when identifying a sequence associated with a particular sequence identification number:

> Claims 13, 24, 25, 27, 28, 29, 30, 43, 45, recite the article "a" or "an" in place of "the" when referring to the sequence represented by a sequence identifier. This is indefinite when referring to a single sequence because reference to a specific sequence would require the use of the article "the". The use of "a" implies that there are multiple sequences to chose from or represented by the sequence identifier, which is not the case when referring to a specific sequence as one is when referencing a sequence identifier.

Despite the Examiner's allegations, claims, 13, 24, 25, 27-30, 43, 45 are believed definite in accordance with the second paragraph of 35 U.S.C. §112.

Applicant include the article "a" or "an" in place of "the" to provide antecedent basis pursuant to §2173.05(e) of the Manual of Patent Examining Procedure (MPEP) , Rev. May, 2004. However, at the Examiner's suggestion, Applicant has substituted the article "the" in claims 13, 24, 25, 27-30, 43, and 45, since Applicant intended to refer to only one sequence, with the understanding the molecule that is hybridizing need not necessarily hybridize to the full extent of the recited sequence. Claims 13, 24, 25, 27-30, 43, and 45 are believed allowable. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 13, 24, 25, 27-30, 43, and 45 under the second paragraph of 35 U.S.C. §112 and that claims 13, 24, 25, 27-30, 43, and 45 be allowed.

In another aspect, the Examiner alleged Applicant's use of "at least about" to characterize the number of bases (length) of a molecule in claims 17 and 18 ad to characterize the number of bases of a sequence to which a molecule hybridizes in claims 14-15 and 19-20 is indefinite. In support of this rejection, the Examiner alleged:

> Claims 14, 15, 17-20 are indefinite for the recitation "at least about" in conjunction with a number of nucleotides which are to hybridize. This recitation

> is indefinite because the lower limits of what are to be encompassed by the claims is not clear. The instant specification does not indicate what range "at least about" is meant to encompass. Furthermore, "at least" is in direct conflict with "about" since "at least" sets a lower limit to the range, but "about" changes that limit. Therefore, the claims are indefinite because the metes and bounds of "at least about" cannot be determined.

Despite the Examiner's allegations, claims, 14-15 and 17-20 are believed definite in accordance with the second paragraph of 35 U.S.C. §112.

The Examiner suggests via a semantics exercise that one reads this as a two part phrase and first decides what range is set by the term "at least" and then would be confused about how to employ the final "about" term." However, this argument is clearly invalid, since the term "at least about X" could alternatively be written as "about X or more." Clearly, no one of ordinary skill in the art would be confused about the meaning of "at least about X" following this straightforward illustration.

Furthermore, rather than the extent of the range, the Examiner's initial comment illustrates the Examiner believes one of ordinary skill in the art would be instead merely be confused about the lower end starting point of the stated range. The issue then comes down to whether one of ordinary skill in the art would understand the meaning of "about 20" or "about 50." Applicant asserts such use of about to allow minor variations from the base number (20 or 50 under the present facts) is commonplace in patent drafting, and the Examiner has not stated adequate facts to demonstrate the existence of any real ambiguity. Applicant sees no basis for believing one of ordinary skill in the art would not reasonably be able to determine the scope of the terminology at issue. The Examiner certainly has not stated any hypothetical facts illustrating or demonstrating that an unreasonably ambiguous situation exists here under the facts of the present application.

Claims 14-15 and 17-20 are believed allowable. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 14-15 and 17-20 under the second paragraph of 35 U.S.C. §112 and that claims 14-15 and 17-20 be allowed.

In yet another aspect, the Examiner alleged Applicant's use of two different phrases amounts to use of two different names for the same thing:

> Claims 13-30 and 38-49 are indefinite for the use of "bovine adipocyte polypeptide leptin" or "bovine leptin polypeptide" (dependent claims are included as well, even if they do not explicitly recite the noted language). These recitations are used separately as well as in conjunction with one another as if to denote a distinction between the molecules which are encoded. However, a fair reading of the instant specification would indicate that the above recitations all refer to the

> same protein, which is leptin produced in cows. Only a single protein is disclosed in the instant specification (SEQ ID NO:4) and there is no disclosure to distinguish one recitation from another. Therefore, the use of these recitations as limitations in the claims is vague and indefinite because the specification discloses that they are the same protein as evidenced by the disclosure at page 5. The metes and bounds of what is being claimed cannot be determined because no differences can be ascertained for the different recitations which appear to mean the same thing.

Despite the Examiner's allegations, Applicant does not believe Applicant's variable usage of "bovine adipocyte polypeptide leptin" or "bovine leptin polypeptide" renders any claim of claims 13-30 and 38-49 indefinite under the second paragraph of 35 U.S.C. §112.

Nonetheless, Applicant agrees with the Examiner's characterization of "bovine adipocyte polypeptide leptin" and "bovine leptin polypeptide" as each referring to bovine leptin produced in cows, and further emphasizes the bovine leptin may be obtained from anywhere such bovine leptin may be found within the cow. Consequently, to satisfy the Examiner's desire for use of common terminology and address the Examiner's previously addressed objection to claims 38-42, 44, and 46, and not for purposes of addressing the present indefiniteness rejection under the second paragraph of 35 U.S.C. §112, Applicant has amended claims 13, 21-22, 24-25, 27-30, and 43 so that claims 13, 22, 24-25, 27-30, and 39-46 all now recite bovine leptin polypeptide. Applicant's action to address the Examiner's previously addressed objection to claims 38-42, 44, and 46 thus moots the Examiner's present basis for rejecting claims 13-30 and 38-49 indefinite under the second paragraph of 35 U.S.C. §112.

Claims 13-30 and 38-49 are each believed allowable. Therefore, Applicant respectfully asks the Examiner to reconsider and withdraw the rejection of claims 13-30 and 38-49 under the second paragraph of 35 U.S.C. §112 and that claims 13-30 and 38-49 be allowed.

Next, the Examiner stated that Applicant's use of the term "stringent hybridization conditions in various claims allegedly render claims 13-30 and 38-49 indefinite:

> Claims 13-30 and 38-49 are indefinite for the limitation of "stringent hybridization conditions". The limitation "stringent hybridization conditions" is equivalent to reciting a range without indicating the metes and bounds of the conditions since there is no indication of what conditions are to be encompassed by the claims. The specification does not provide a definition of what conditions are considered "stringent" and the art recognizes a multitude of conditions which could be used and considered "stringent". . . . Hybridization conditions are found in the specification in conjunction with Example II, however, the specification

> does not disclose that these conditions are what is intended by the recitation of "stringent hybridization conditions".

Despite the Examiner's allegations, Applicant does not believe use of the "stringent hybridization" terminology renders any claim of claims 13-30 and 38-49 indefinite under the second paragraph of 35 U.S.C. §112.

Though the term "stringent hybridization conditions" may be broad and encompass a wide variety of complementary or individually sufficient conditions; however, mere use of broad terminology does not render a claim indefinite. The question is whether one of ordinary skill in the art would understand what is meant by stringent hybridization conditions. In this regard, a hard and fast definition is unnecessary if those of ordinary skill in the art would understand what is meant by stringent hybridization conditions.

The Examiner acknowledges that there are many routes to attaining stringent hybridization conditions:

> . . . the Declaration and the arguments which accompany it demonstrate that there are a multitude of conditions which the prior art and those skilled in the art recognize as being "stringent hybridization conditions". Varying the length of the probe, the temperature at which the hybridization occurs, the salt concentration at various stages including wash steps and varying denaturing agents can all provide different specificities in hybridization. Without knowing which conditions are intended by the claims, the metes and bounds of those molecules which are encompassed by the claims cannot be determined.
>
> . . .
>
> However, in the absence of a true definition in the specification that indicates what conditions are intended by 'stringent", the rejection is maintained as it is clearly supported by Applicant's arguments and the Declaration filed that there are a number of variables involved in hybridization, and therefore, a number of different conditions which would provide for "stringent" hybridization.

However, the mere fact that there are alternative approaches to attaining stringent hybridization conditions does not demonstrate any confusion about the meaning of the "stringent hybridization" terminology. It instead merely demonstrates one of ordinary skill in the art has different options for attaining stringent hybridization conditions. The Examiner's demonstration that there are plenty of alternative approaches to attaining "stringent hybridization conditions" does not support the Examiner's contention that the "stringent hybridization terminology" is confusing or indefinite. The fact that there are alternatives does not show the existence of

confusion; Indeed, the Examiner produces no evidence showing one of ordinary skill in the art would be confused about the meaning of the "stringent hybridization conditions" terminology.

The Examiner alleges, or at least implies, Applicant's use of the "stringent hybridization conditions" terminology amounts to reading specification details into the claims:

> Applicant makes many references to the conditions in Examples II and III of the specification, however, imitations from the specification cannot be read into the claims. Applicant may wish to include the conditions which are exemplified in Examples II and III into the claims in order to avoid the rejection of record.

However, the mere fact that one of ordinary skill in the art may look to the specification for some alternative approaches to attaining stringent hybridization conditions beyond conditions they are accustomed to using does not render the "stringent hybridization condition" terminology indefinite. Furthermore, the "stringent hybridization terminology" does not require one of ordinary skill in the art to use any of the alternative approaches described in the specification.

Finally, the Examiner alleged the Declaration Under 37 CFR 1.132 filed on December 16, 2004 was insufficient to overcome the indefiniteness rejection stated in the June 6, 2004 Office Action:

> Applicant argues this rejection beginning at page 24 through page 46 of the response. The Declaration under 37 CFR 1.132 filed 16ecember 2004 is insufficient to overcome the rejection of claims 13-30 and 38-49 based upon indefiniteness as set forth in the last Office action (as applied to the previous filed claims) because: the Declaration and the arguments which accompany it demonstrate that there are a multitude of conditions which the prior art and those skilled in the art recognize as being "stringent hybridization conditions".

Applicant notes the Declaration referenced by the Examiner was merely included to demonstrate the specification of the above-identified application, based on the understanding of hybridization stringency at the time the priority application was filed, provides ample support for the 'stringent hybridization conditions" terminology recited in the claims.

The Examiner reaches an erroneous conclusion about some discussion included in the present application regarding stringent hybridization conditions:

> Page 8 of the specification makes reference to hybridization that "[I]n order to achieve higher specificity of hybridization, characterized by the absence of hybridization to sequences other than those encoding the polypeptide or a functional derivative thereof, a length of at least about 50 nucleotides is preferred". Based on this language, it would seem that claims that include the

> limitation of "at least about 20 nucleotides" would be in direct conflict with the limitation that "stringent hybridization conditions" are used.

The statements cited by the Examiner are not in direct conflict with each other, despite the Examiner's contention to the contrary. First, Applicant notes the "at least about 50 nucleotides" characterization is preferred, and not required. Certainly, the Examiner is aware that varying (increasing) the length of the probe is one approach to enhancing stringency of hybridization conditions, since the Examiner mentioned "[v]arying the length of the probe" as one way of varying hybridization stringency later at the bottom of page 13 of the present Office Action. Certainly, the Examiner recognizes that approaches other than probe length can be taken to enhance hybridization stringency. This demonstrates the limitation of "at least about 20 nucleotides" is not "in direct conflict with the limitation that 'stringent hybridization conditions' are used."

Though the term "stringent hybridization conditions" may be broad and encompass a wide variety of complementary or individually sufficient conditions, the use of broad terminology does not necessarily render a claim indefinite. The Examiner acknowledges that there are many routes to attaining stringent hybridization conditions. But as explained above, the mere fact that there are alternatives does not demonstrate the underlying terminology is indefinite. Despite the Examiner's many allegations and contentions, the Examiner produces no evidence showing one of ordinary skill in the art would be confused about the meaning of the "stringent hybridization conditions" terminology and therefore fails to establish the "stringent hybridization conditions" terminology is indefinite.

Claims 13-30 and 38-49 are each believed allowable. Therefore, Applicant respectfully asks the Examiner to reconsider and withdraw the rejection of claims 13-30 and 38-49 under the second paragraph of 35 U.S.C. §112 and that claims 13-30 and 38-49 be allowed.

Finally, the Examiner persists with the allegation that use of the "substantially all" terminology in claims 16, 21, 23-24, and 26-29 renders claims 21, 23-24, and 26-29 indefinite:

> Claims 16, 21, 23, 24, 26, 28, 29 are directed to nucleic acid molecules (DNA, mRNA) which "hybridizes" to `substantially air of the bases of a recited sequence. However, these claims are indefinite for the failure to indicate what is intended by the recitation `substantially all.

Despite the Examiner's allegations, Applicant does not believe use of the "substantially all" terminology renders any claim of claims 21, 23-24, and 26-29 indefinite under the second paragraph of 35 U.S.C. §112.

In response to Applicant's notation that applications handled by the Examiner have issued into U.S. patents with claims that employ "substantially all" terminology:

> For example, claim 1 of U.S. Patent No. 6,756,484 employs the "substantially all" terminology more than five different times. In one instance, claim 1 recites:
>
> (C) . . . with a sufficient quantity of a first cation exchange elution buffer, which has a sufficiently high pH or ionic strength to displace **substantially all** of said authentic and non-authentic IGF-I from said cation exchange matrix . . . .
>
> Emphasis added. Applicant's review of U.S. Patent No. 6,756,484 did not identify any particular numeric meaning or degree of identity for this use of the "substantially all" terminology.

In response, the Examiner merely stated that "each application is examined on its own merits" and "[t]he facts surrounding the issued patent are not the same and are not applicable to the instant application." This is an unsatisfactory response because the Examiner failed to explain why the facts of U.S. Patent No. 6,756,484 would allow use of "substantially all" terminology in the claims without identifying any particular numeric meaning or degree of identity for this use of the "substantially all" terminology, whereas the Examiner now demands identification of a particular numeric meaning or degree of identity in order to allow Applicant's use of the "substantially all" terminology. Further explanation for this distinction between the facts pertaining to U.S. Patent No. 6,756,484 versus the facts of the present application that would support the differential treatment sought by the Examiner is respectfully requested.

The Courts do not require that any particular numeric meaning be provided for a claim containing the "substantially all" terminology to be definite. The Examiner asks "what degree of identity is intended" for Applicant's use of the "substantially all" terminology in the claims at issue. However, like numeric meaning, the Courts do not require that any "degree of identity" be provided for a claim containing the "substantially all" terminology to be definite. Rather, the question is whether those skilled in the art will be able to understand with a *reasonable* degree of accuracy what subject matter is circumscribed by the invention that is defined by a particular claim, such as claim 16. Also, the issue is not whether the particular

terminology is definite, but rather whether the meaning of the claim containing the terminology at issue is definite. The remaining argument provided in the Amendment After Final filed on December 16, 2004 is hereby incorporated by reference. The comments provided therein are thought to adequately address the Examiner's current comments on pages 14-16 regarding the rejection of claims containing "substantially all" terminology. Furthermore, as explained above, the Examiner's contentions about the "stringent hybridization terminology" being indefinite are unsupported and erroneous.

The foregoing comments along with the comments referred to in the Amendment After Final filed December 16, 2004 demonstrate one of ordinary skill in the art of microbiology would be able to understand, with a *reasonable* degree of accuracy, what subject matter is circumscribed by the invention defined by claims 16, 21, 23-24, 26 and 28-29 which employ the "substantially all" terminology. First, the meaning of the term "substantially all" clearly means something less than "all," yet more than "half." Beyond this, the "under stringent hybridization conditions" terminology of claims 16, 21, 23-24, 26 and 28-29 provide ample further guidance. Specifically, one of ordinary skill in the art would understand the "substantially all" term of claims 16, 21, 23, 24, 26 and 28-29 characterizes the high ("perfect or near perfect") degree to which the DNA probe base-pairs to the target DNA molecule.

Claims 16, 21, 23, 24, 26 and 28-29 are believed allowable. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 16, 21, 23, 24, 26 and 28-29 under the second paragraph of 35 U.S.C. §112 and that claims 16, 21, 23, 24, 26 and 28-29 be allowed.

Claim Rejection Under 35 U.S.C. §102(a) Based on the Tellam Submission

In the Office Action, the Examiner rejected claims 25-30, 41-42, and 45-49 under 35 U.S.C. 102(a) as allegedly being anticipated by Genbank ACC. No. U43943, Bos Taurus OBESE mRNA submission dated January 1996, hereinafter referred to as the "Tellam submission." Despite this rejection, Applicant continues to believe claims 25-30, 41-42, and 45-49 are allowable over the Tellam submission, as explained more fully below.

In the present Office Action, the Examiner provided the following additional comments regarding this rejection:

> Applicant asserts that the Declaration under 37 CFR 1.131 is sufficient to overcome the instant rejection. MPEP 715.03(b) states that proof of prior completion of a species different from the species of the reference will be sufficient to overcome a reference indirectly under 37 CFR 1.131 if the species shown in the reference would have been obvious in view of the species shown to have been made by the application. However, the species in the reference would not have been obvious in view of the species in the instant application, absent evidence to the contrary and in view of current case law governing biotech applications. Alternatively, the applicant may be able to antedate the reference indirectly by, for example, showing prior completion of one or more species which put him or her in possession of the claimed genus prior to the reference's date. Applicant has not successfully done this for a number of reasons.
>
> Applicant first argues that the Examiner did not give sufficient explanation of why the first Declaration was insufficient to overcome the rejection based on TELLAM et al. First, the relationship of the different Exhibits does not make sense. The sequence alignments of Exhibits D and E appear to be with the nucleic acid molecule of the instant application. The sequence of Exhibit C cannot be determined because the copy is so poor; the left hand portion is unreadable. Lastly, the correspondence of the "450 base pair clone" to the nucleic acid sequence of the instant application is in question. It is not clear if the nucleic acid molecule of this clone would hybrids to the nucleic acid molecule of SEQ ID NO:3. Applicant is invited to provide a clear line of explanation as to the sequence of this clone (i.e. a clear copy of the nucleic acid sequence with an indication of the orientation of the molecule) as well as evidence, possibly sequence alignment, which shows that it is within the claimed genus. In the Declaration filed 16 December 2004, paragraph H attempts to relate the sequence of the clone (450 bp clone) to the nucleic acid molecule of SEQ ID NO:3 of the instant application. However, the Examiner cannot make the sequence line up as asserted, and the arguments presented do not make sense in the context of sequences which do not align. Therefore, the Declaration is not sufficient to overcome the rejection based on this reference.

First, Applicant wishes to point out the Examiner's reference to the Sequence Alignments of Exhibits D and E indicates the Examiner was looking at a copy of a 131 Declaration and related exhibits that was itself cited in the first 132 Declaration submitted in the present application. The Examiner should instead be looking only at the 131 Declaration submitted on December 16, 2004 and its attached Exhibits. Applicant has again taken a look at the 131 Declaration submitted on December 16, 2004 and its Exhibits and did not encounter the confusion the Examiner expressed. Consequently, Applicant's undersigned attorney, Philip F. Fox, would like to have a teleconference with the Examiner to alleviate the Examiner's confusion over the correspondence of the various sequences mentioned in the 131 Declaration submitted on

December 16, 2004. Applicant's undersigned attorney, Philip F. Fox, will contact the Examiner within a few days to schedule this teleconference and confirm beforehand the Examiner has the 131 Declaration and Exhibits to be discussed during the teleconference.

As the Examiner noted in her comments provided in the June 16, 2004 Office Action in support of the anticipation rejection based on the Tellam submission:

> . . . applicant may be able to antedate the reference indirectly by, for example, showing prior completion of one or more species which put him or her in possession of the claimed genus prior to the reference's date.

Applicant is confident the proposed teleconference will resolve the Examiner's concerns about the 131 Declaration submitted on December 16, 2004. This will put Applicant in possession of a first species falling within the scope of claims at issue prior to the effective date of the Tellam submission. Additionally, Applicant was in possession of a second species, the species of SEQUENCE ID NO. 3, since the priority application the present application is based upon (U.S. Patent Application No. 08/688,908 (now U.S. Patent No. 6,297,027)) was filed less than one year after the effective date of the Tellam submission. Based on possession of one or both of these species, the question, analogous to the question central to the Written Description inquiry, is whether one of ordinary skill in the art would recognize that still other related species falling within the claims were in possession of the inventor prior to the effective date of the Tellam reference.

The answer to this question is yes. The claims and the application disclose use of stringent hybridization conditions. Such use of stringent hybridization conditions is known in the art to yield structurally similar molecules such that one of ordinary skill in the art would not expect substantial variation among species encompassed within the scope of the claims. Indeed, even just the disclosed species of SEQUENCE ID NO. 3 that the Examiner has acknowledged, considered along with the stringent hybridization conditions defined in the claims and the level of skill and knowledge in the art, are sufficient to allow the skilled artisan to recognize the inventor was in possession of the necessary common attributes or features of the elements possessed by the members of the genus prior to the effective date of the Tellam reference. This analysis dovetails with the analysis provided for analogous fact patterns in Examples 9 and 10 in the Synopsis of Application of Written Description Guidelines available at http://www.uspto.gov/web/menu/written.pdf. The foregoing comments demonstrate the inventor

did in fact have possession of the invention of the present application, as presently defined in the claims of the above-identified application, prior to the effective date of the Tellam reference.

Because the present invention, as defined in claims 25-30, 41-42, and 45-49 was in the possession of the inventor on or before December 26, 1995 and therefore prior to the effective date of the Tellam submission, the Tellam submission does not anticipate the invention of the above-identified application, as defined in claims 25-30, 41-42, and 45-49. Claims 25-30, 41-42, and 45-49 are each believed allowable. Consequently, Applicant respectfully requests that the Examiner reconsider and withdraw the rejections of claims 25-30, 41-42, and 45-49 under 35 U.S.C.§102(a) based on the Tellam submission and that claims 25-30, 41-42, and 45-49 be allowed.

Claim Rejections Under 35 U.S.C. §103(a) Based on the Tellam Submission

In the Office Action, the Examiner rejected claims 13-24, 38-40, and 43-44 under 35 U.S.C. 103(a) as allegedly being obvious in light of the Tellam submission. The Examiner did not provide any further argument in support of this rejection in the present Office Action beyond alleging the 131 Declaration filed December 16, 2004 had not yet overcome this rejection. Despite the Examiner's comments, the Tellam submission does not teach, suggest, disclose, or render obvious the invention of the above-identified application, as defined in claims 13-24, 38-40, and 43-44.

As indicated above, claim 38 has been cancelled, since claim 38, after amending to address the Examiner's objection to claim 38, was merely a duplicate of claim 13. Applicant's cancellation of claim 38 is in no way related to the Examiner's rejection of claim 38 under 35 U.S.C. 103(a) based on the Tellam submission.

As noted in the Amendment After Final filed on December 16, 2005, the Examiner has failed to state a prima facie case for the alleged obviousness of attaining the invention of the above-identified application, as defined in claims 13-24, 38-40, and 43-44, based on the very limited disclosure of the Tellam submission. According to the Examiner, it would have been obvious to one of ordinary skill in the art to use the mRNA molecule of TELLAM et al. to generate a DNA molecule. However, the mere disclosure of the mRNA molecule in Tellam in accordance with the Examiner's comments does not teach or suggest the

Examiner's alleged transformation to the complementary cDNA molecule. That teaching or suggestion must necessarily come from outside of the Tellam submission and apparently came by virtue of hindsight reconstruction using the above-identified application as a road map. Such hindsight reconstruction is never an appropriate basis for alleging obviousness.

Furthermore, for reasons analogous to those provided above in relation to the Examiner's .§102 rejection based on the Tellam submission, the present invention, as defined in claims 13-24, 38-40, and 43-44 was in the possession of the inventor on or before December 26, 1995 and therefore prior to the effective date of the Tellam submission. Consequently, the Tellam submission does not render obvious the invention of the above-identified application, as defined in claims 13-24, 38-40, and 43-44.

Claims 13-24, 38-40, and 43-44 are believed allowable. Consequently, Applicant respectfully requests that the Examiner reconsider and withdraw the rejections of claims 13-24, 38-40, and 43-44 under 35 U.S.C.§103(a) based on the Tellam submission and that claims 13-24, 38-40, and 43-44 be allowed.

Claim Rejections Under 35 U.S.C. §103(a) Based On The Friedman Patent

In the Office Action, the Examiner continues to reject claims 21-30 and 38-49 under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent N. 6,309,853 to Friedman et al. (subsequently referred to as the "Friedman patent"). In support of this rejection, the Examiner now states:

> The instant specification defines a functional derivative as
>
> > Any "fragment", "variant", "analog", or "chemical derivative" of the bovine adipocyte polypeptide that retains at least a portion of the function of the bovine adipocyte polypeptide which permits its utility in accordance with the present invention. (page 7 of the specification)
>
> The instant claims are directed to isolated nucleic acids which encode bovine leptin or a "functional derivative thereof" or `variant thereof. The prior art of Friedman et al. (U.S. Pat No. 6,309,853) disclose nucleic acids which encode human and mouse leptin, which would be considered functional derivatives and/or variants of the disclosed bovine leptin since they encode leptin molecules and would possess similar functional properties as those of the bovine leptin, absent evidence to the contrary. Friedman at al. teach that the leptin gene (or OB)

> could be isolated from domestic animals using the methods disclosed therein (see column 26, line 53 to column 27, line 49). Friedman et al. specifically mention cows as a domestic animal for which leptin would be useful (see column 48, lines 41-57). Friedman et al. do not specifically disclose an isolated nucleic acid encoding a bovine leptin polypeptide. However, it would have been obvious to use the nucleic acid of Friedman et al. encoding human or mouse leptin and hybridize it to a. bovine cDNA library and isolate a nucleic acid molecule encoding porcine leptin because Friedman et al. teach methods for isolating leptin encoding nucleic acids and also teach that it would be beneficial to administer leptin to cows. It would also have been prima facie obvious to use the nucleic acid of Friedman at al. encoding human or mouse leptin and hybridize it to bovine genomic DNA to isolate the gene encoding bovine leptin because it would have been beneficial to more completely understand the gene structure of bovine leptin. ft also would have been prima facie obvious to use the nucleic acid of Friedman at al. encoding human or mouse leptin and hybridize it to bovine mRNA to isolate the mRNA encoding porcine leptin for the benefit of understanding the nature of bovine leptin expression. Therefore, the invention as a whole would have been obvious at the time it was made, absent evidence to the contrary.

Despite the Examiner's allegations, the Friedman patent does not teach, suggest, disclose, or make obvious the invention of the above-identified application, as defined in claims 21-30 and 39-49.

As indicated above, claim 38 has been cancelled, since claim 38, after amending to address the Examiner's objection to claim 38, was merely a duplicate of claim 13. Applicant's cancellation of claim 38 is in no way related to the Examiner's rejection of claim 38 under 35 U.S.C. 103(a) based on the Friedman patent.

As noted above, the Friedman patent does not teach, suggest, or disclose the invention of the above-identified application, as defined in claims 21-30 and 39-49. Consistent with the Examiner's observation, the Friedman patent does disclose murine and human leptin DNA sequences and polypeptides. Also, consistent with the Examiner's observation, the Friedman patent does not disclose any bovine leptin DNA (or mRNA) molecules or polypeptides. Furthermore, consistent with the Examiner's observation, the Friedman patent does not disclose any functional derivative or variant DNA (or mRNA) molecules that encode for bovine leptin polypeptide.

For example, when recombinant growth hormone is administered by injection to castrate male cattle, the castrate male cattle exhibit <u>increased</u> adipose tissue leptin mRNA expression. On the other hand, when recombinant growth hormone is administered by injection

to male mice, the male mice exhibit essentially no increased adipose tissue leptin mRNA expression. Based on the documented differences in adipose tissue leptin mRNA expression after administration to normal male cows (per the previously cited Spurlock publication) versus normal male rats (per the previously cited Lee publication), it is evident that bovine leptin surprisingly functions very differently after administration of growth hormone to male cattle as compared to how rat leptin functions after administration of growth hormone to male rats.

As another example, when dexamethasone (a glucocorticoid) is administered to multiparous non-lactating Holstein cows, the dexamethasone administration fails to change plasma leptin protein levels. On the other hand, when dexamethasone is administered to healthy human volunteers, the healthy human volunteers exhibit significantly increased leptin expression in the serum after dexamethasone administration. Since dexamethasone administration fails to change plasma leptin concentrations in cows, while dexamethasone administration significantly increased serum leptin levels in healthy human volunteers, it is evident bovine leptin based on the documented differences in bovine leptin protein expression after dexamethasone administration to normal cows (per the Spurlock publication) versus human leptin protein expression after dexamethasone administration to healthy human volunteers (per the Fried publication), it is further evident that bovine leptin protein surprisingly functions very differently from human leptin protein.

The Examiner suggests the Friedman patent "discloses nucleic acids which encode human and mouse leptin, which would be considered functional derivatives and/or variants of the disclosed bovine leptin since they encode leptin molecules and would possess similar functional properties as those of the bovine leptin, absent evidence to the contrary." Applicant has provided such evidence demonstrating that Friedman nucleic acids which encode human and mouse leptin do not possess similar functional properties as the properties of bovine leptin. Applicant's factual evidence illustrates the human leptin disclosed in the Friedman patent does not, despite the Examiner's contentions to the contrary, necessarily, or actually, possess functional properties similar to the functional properties of the bovine leptin disclosed in the above-identified application. Nonetheless, in response to this presentation of differing properties, the Examiner switched horses and basically alleged Applicant could only consider functional properties disclosed for bovine leptin in the present application.

This is an erroneous and overly restrictive view by the examiner. The evidence Applicant presented demonstrates functional differences between the Freidman leptin and bovine leptin. The fact that those differences exist with some functional attributes raises serious doubts about the correspondence in other functional attributes, such as those disclosed in the present application, despite the Examiner's attempt to avoid this evidence. Consequently, it is clear Applicant has rebutted the Examiner's prima facie case of obviousness and it is the Examiner's obligation to now withdraw the present rejection or present contrary evidence demonstrating correspondence in other functional attributes between the Freidman leptin and bovine leptin

Furthermore, based on the factual results noted above and despite the Examiner's contentions to the contrary, the Examiner's speculative suggested hybridization of the nucleic acid of the Friedman patent that encodes murine leptin to a bovine DNA library and subsequent isolation of a nucleic acid molecule encoding bovine leptin is not suggested since the functional characteristics of the murine leptin disclosed in the Friedman patent would not confirm isolation of a nucleic acid molecule encoding for bovine leptin, as claimed in the above-identified application.

Finally, despite the Examiner's contentions to the contrary, the Examiner's speculative suggested hybridization of the nucleic acid of the Friedman patent that encodes human leptin to a bovine DNA library and subsequent isolation of a nucleic acid molecule encoding bovine leptin is not suggested. Any alleged suggestion fails to exist since the functional characteristics of the human leptin disclosed in the Friedman patent would not confirm isolation of a nucleic acid molecule encoding for bovine leptin, as claimed in the above-identified application.

Claims 21-30 and 38-49 are believed allowable. Consequently, Applicant respectfully requests that the Examiner reconsider and withdraw the rejections of claims 21-30 and 38-49 under 35 U.S.C.§103(a) based on the Friedman patent and that pending claims 21-30 and 38-49 be allowed.

New Claims Added by Applicant

Applicant has added new claims 50-51. New claims 50-51 do not add any new matter to the above-identified application. Support for new claims 50-51 is believed to exist

throughout the above-identified application. Applicant respectfully requests consideration and allowance of new claims 50-51.

CONCLUSION

Claims 13-30 and 39-51 are believed allowable. Therefore, reconsideration and allowance of claims 13-30 and 39-49 is respectfully requested. Likewise, consideration and allowance of new claims 50-51 is respectfully requested. The Examiner is invited to contact Applicant's below-named attorney, Philip F. Fox, to facilitate allowance of the above-identified application.

Respectfully submitted,

Date: August 10, 2005 By _____

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